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(54) Title: STENT DELIVERY SYSTEM
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(57) Abstract

A stent delivery system with a stabilizing manipulator handle (20) is disclosed. The system has a self-expanding stent (14) in a contracted condition disposed on the distal end (11) of a delivery catheter (10) and a retractable sheath (16) covering the stent (14). The delivery catheter (10) is advanced through a guiding catheter (38) to a desired location within a patient's body lumen. The manipulator handle (20) at the proximal end (13) of the delivery catheter (10) is attached to the guiding catheter (38) . The handle (20) has a slidable stem (30) connected to the sheath (16), and features a screw down spacer between the distal end of the handle and the proximal end (21) of the guiding catheter. The spacer (40) situates the position of the guiding catheter (38) relative to the delivery catheter (10) even during deployment of the stent (14). Once the stent (14) is at the targeted site, the sheath (16) is retracted by pulling back on the stem (30) to expose the self-expanding stent (14). A stop (18) on the interior of the delivery catheter (10) positioned proximal to the stent (14) further prevents the latter from moving out of position when the sheath (16) is retracted.

(57) Abrégé

Cette invention se rapporte à un système d'application d'extenseurs pourvu d'un manche de manipulation stabilisateur (20), qui comprend un extenseur autodilatable (14) à l'état contracté, disposé sur l'extrémité distale (11) d'un cathéter d'application (10) et une gaine rétractable (16) couvrant le cathéter (14). Le cathéter d'application (10) est amené à avancer dans un cathéter de guidage (38) jusqu'à une position souhaitée à l'intérieur d'un passage corporel du patient. Le manche de manipulation (20) à l'extrémité proximale (13) du cathéter d'application (10) est fixé au cathéter de guidage (38). Le manche (20) possède une tige coulissante (30) reliée à la gaine (16) et comporte un élément d'espacement à vis placé entre l'extrémité distale du manche et l'extrémité proximale (21) du cathéter de guidage. Cet élément d'espacement (40) situe la position du cathéter de guidage (38) par rapport au cathéter d'application (10) même pendant le déploiement de l'extenseur (14). Une fois l'extenseur (14) amené à l'endroit voulu, on retire la gaine (16) en tirant la tige (30) vers l'arrière pour exposer l'extenseur autodilatable (14). Une butée (18) placée à l'intérieur du cathéter d'application (10) à proximité de l'extenseur (14) empêche en outre celui-ci de sortir de sa position, lors du retrait de la gaine (16).

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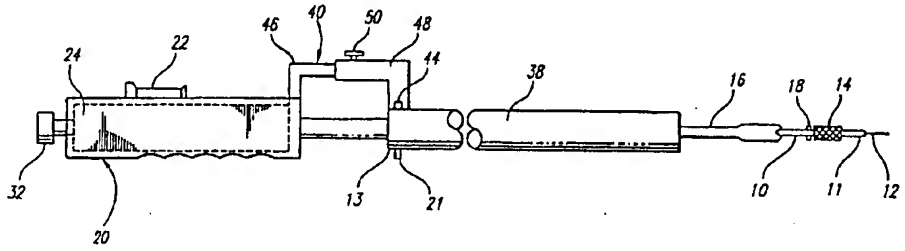

(57) Abstract

A stent delivery system with a stabilizing manipulator handle (20) is disclosed. The system has a self-expanding stent (14) in a contracted condition disposed on the distal end (11) of a delivery catheter (10) and a retractable sheath (16) covering the stent (14). The delivery catheter (10) is advanced through a guiding catheter (38) to a desired location within a patient's body lumen. The manipulator handle (20) at the proximal end (13) of the delivery catheter (10) is attached to the guiding catheter (38). The handle (20) has a slidable stem (30) connected to the sheath (16), and features a screw down spacer between the distal end of the handle and the proximal end (21) of the guiding catheter. The spacer (40) situates the position of the guiding catheter (38) relative to the delivery catheter (10) even during deployment of the stent (14). Once the stent (14) is at the targeted site, the sheath (16) is retracted by pulling back on the stem (30) to expose the self-expanding stent (14). A stop (18) on the interior of the delivery catheter (10) positioned proximal to the stent (14) further prevents the latter from moving out of position when the sheath (16) is retracted.

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Description

STENT DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

The present invention relates in general to the delivery of stents into a body lumen, such as a blood vessel, to maintain the patency thereof. More particularly, the present invention relates to an improved stent delivery system which can quickly and accurately position a self-expanding stent into a body lumen.

In a medical procedure known as percutaneous transluminal coronary angioplasty (PTCA), a balloon catheter is used to dilate the lumen of a coronary artery which has become narrowed or restricted due to the accumulation of atherosclerotic plaque along the artery wall. In the PTCA procedure, a balloon catheter is advanced through the vasculature to the stenosis and the balloon is inflated to radially compress the atherosclerotic plaque against the inside of the artery wall. The balloon then is deflated so that the dilation catheter can be removed and blood flow resumed through the dilated artery.

Occasionally, the inflation of the balloon within the artery lumen will dissect either the stenotic plaque or the intima of the blood vessel or both. After the balloon is deflated and removed, blood can flow between the arterial wall and the dissected lining thereby constricting the flow passage or causing a section of the dissected lining, commonly called an "intimal flap," to be forced into the flow passageway. In the event of partial or total occlusion of a coronary artery by a dissected arterial lining, the patient is put in an extremely dangerous situation requiring immediate medical attention, particularly when the occlusion occurs in one of the coronary arteries.

Another problem which frequently arises after an angioplasty procedure is the appearance of a restenosis at or near the site of the treated artery. The restenosis may appear due to the accumulation of additional atherosclerotic plaque or may be the result of weakened arterial walls which have collapsed inwardly to restrict blood flow. When restenosis appears, the treated patient may require an additional

angioplasty procedure or other treatment such as by-pass surgery, if an additional angioplasty procedure is not warranted.

Due to the problems caused by dissections of the arterial lining or the appearance of restenosis, much research has been performed on ways to maintain the patency of an artery after the angioplasty procedure is completed. In recent years, expandable endoprosthetic devices, commonly called "stents," have gained widespread acceptance as a means to support the arterial walls and maintain the patency of a treated vessel. Stents are generally cylindrically shaped intravascular devices which are placed within a damaged artery to hold it open and maintain unimpeded blood flow. Stents prevent dissected arterial linings from occluding an artery by pressing the dissected tissue against the arterial wall until natural healing results in the re-securing of the dissected tissue to the arterial wall. Stents also prevent the appearance of restenosis in the treated vessel by supporting the weakened arterial walls.

Various means have been developed for delivering and implanting intravascular stents within a body lumen. One common method involves compressing or otherwise reducing the diameter of a self-expanding stent, mounting the compressed stent on the distal end of a delivery catheter, placing a tubular sheath over the stent to restrain the stent in the contracted condition, and advancing the catheter through the patient's vasculature to the desired location. Once the stent is properly positioned, the stent is exposed by withdrawing the sheath proximally with respect to the stent, advancing the stent distally with respect to the sheath, or performing a combination of both. Once free from the sheath, the self-expanding stent expands against the arterial walls to thereby hold open the artery or other body lumen into which it is placed.

Another example of a stent delivery system is described in U.S. Patent No. 5,026,377 to Burton et al. Burton et al. discloses an instrument for deploying or retracting of a self-expanding stent in a body canal, which instrument comprises an elongated tubular outer sleeve having disposed therein an elongated core which is

moveable relative to the sleeve and which has a grip member formed at or near its distal end, which grip member is adapted to releasably hold a self-expanding stent within the outer sleeve.

U.S. Patent No. 5,190,058 to Jones et al. discloses a method of using a temporary stent catheter. The catheter comprises a catheter tube having a distal end and a proximal end, and an elongated balloon which can be inflated by fluid pressure attached to the catheter tube near its distal end. A stent having a tubular configuration is attached to the catheter tube near its distal end and surrounds the balloon. A pressurization device is provided near the proximal end of the catheter tube for inflating and deflating the balloon, whereby the stent may be pressed against the wall of a blood vessel by inflating the balloon and the balloon subsequently may be deflated. A restriction device is provided near the proximal end of the catheter tube for maintaining the stent in an expanded condition and for subsequently effecting the radial contraction of the stent whereby it may be removed from the blood vessel.

U.S. Patent No. 5,201,757 to Heyn et al. discloses an apparatus for deploying a radially self-expanding stent that includes proximal and distal sleeves respectively containing proximal and distal end portions of the stent in a reduced radius delivery configuration. Once the stent and sleeves are positioned at the intended fixation site, the sleeves are moved axially with respect to one another to permit radial self-expansion of the stent only over its medial region, while the sleeves continue to contain the axially outward regions of the stent. Upon sufficient movement of the sleeves axially relative to one another, the stent becomes totally free of the sleeves.

U.S. Patent No. 5,290,295 to Querals et al. discloses a tool for the intraluminal insertion and deployment of a tubular graft within a blood vessel, which tool is constructed to have a flexible insertion shaft with a tapered distal end, a tubular sheath, a deployment slider, and a safety locking tube.

U.S. Patent No. 5,391,172 to Williams et al. discloses a stent delivery system with coaxial catheter handle. The catheter handle, via a thumb switch, provides

relative motion between the outer sheath of a stent delivery catheter and an underlying catheter, to enable the outer sheath to be withdrawn from over the underlying catheter and to expose a vascular prosthesis.

U.S. Patent No. 5,507,768 to Lau et al. discloses a stent delivery method and system that includes an elongated delivery sheath and a catheter disposed within an outer lumen of the sheath and having an expandable member on its distal extremity. An expandable stent is mounted on the expandable member, the distal portion of the sheath tapers down and is tucked within an elastic cone during transport of the stent to a stenotic region. A manipulating device is provided on the proximal end of the delivery system to effect relative axial movement between the sheath and the catheter so as to expose the stent mounted on the expandable member on the catheter within a body lumen such as a coronary artery and to allow the expansion of the stent by the expansion of the expandable member.

One of the difficulties with some prior art self-expanding stents involves deploying the stent at the precise, desired location within the body lumen. Typically, a self-expanding stent is mounted on the distal end of a delivery catheter which is attached to a manipulator handle outside the patient's body. The stent is deployed by actuating a mechanism on the manipulator handle, such as a thumb plate, which is hand operated by the physician. When the thumb plate is withdrawn proximally relative to the manipulator handle, the sheath is withdrawn proximally relative to the catheter and stent.

The problem arises when the operator applies a proximal force to move the thumb plate, a counteracting distal force is normally applied to the manipulator handle thereby making it very difficult to hold the manipulator handle steady. If the handle is inadvertently moved while the sheath is retracted, the stent may not be deployed in the desired location. As a result, the ends of the stent may damage the vessel by pushing into the vessel wall. In addition, a poorly placed stent may do more harm than good and can be very difficult to retrieve once deployed. Therefore, it is critical to position the stent accurately on the first attempt.

What has been needed and heretofore unavailable is a delivery system for self-expanding stents which provides a means to fix the position of the manipulator handle during the stent deployment process to prevent unwanted movement and to provide greater accuracy of stent placement within a body lumen. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to a stent delivery system which provides for improved accuracy of stent placement within a body lumen by preventing unwanted axial movement of the manipulator handle during the delivery and deployment of a self-expanding stent. The present invention in a preferred embodiment comprises an elongated catheter body having an inner lumen extending therein which is adapted to receive a guide wire. A cylindrically shaped, self-expanding intravascular stent is slidably disposed on the exterior of the distal end of the catheter. The catheter and stent are slidably disposed within the lumen of an elongated tubular sheath formed at the distal end to receive telescopically the self-expanding stent and to hold it in a contracted condition during delivery. A manipulator handle is attached to the proximal end of the catheter and includes a slidable element which is connected to the proximal end of the tubular sheath. A guiding catheter is provided to facilitate advancement of the delivery assembly through the patient's vasculature to the treatment site.

Once the stent is delivered to the desired location within the patient's vasculature, a coupling device on the manipulator handle allows the operator to fix the axial position of the manipulator handle relative to the guiding catheter. The coupling device may be in the form of an adjustable length arm which releasably attaches the manipulator handle to the guiding catheter thereby anchoring the axial position of the manipulator handle. With the manipulator handle anchored to the guiding catheter, the operator may retract the sheath by withdrawing the slidable switch without being concerned about inadvertently moving the manipulator handle

in the process. Therefore, the operator may focus on the stent deployment rather than on holding the manipulator handle steady.

In a typical procedure, a guiding catheter is introduced percutaneously into the patient's arterial system and is advanced until the distal tip of the catheter is disposed in the ostium of a coronary artery. The stent delivery system and a guide wire which has been slidably disposed within the lumen of the catheter are advanced through the guiding catheter to the distal end thereof. The guide wire is advanced out of the distal tip of the guiding catheter into the patient's coronary anatomy until the distal tip of the guide wire reaches the desired arterial location. The stent delivery system is then advanced over the guide wire until the stent reaches the desired position. A coupling device is used to attach the manipulator handle to the proximal end of the guiding catheter such that the manipulator handle is prevented from moving relative to the guiding catheter. The sheath is then withdrawn proximally by pulling back on the slidable switch located on the manipulator handle to expose the self-expanding stent. A stop may be located on the catheter just proximal of the stent to prevent the stent from sliding proximally relative to the catheter due to frictional engagement with the sheath. When the sheath is retracted, the self-expanding stent located on the distal end of the catheter is exposed thereby allowing the stent to expand against the vessel wall.

Because the manipulator handle is attached to the guiding catheter, the axial position of the catheter and the stent are not affected while manipulating the switch on the manipulator handle to retract the sheath. The coupling device holds the catheter steady during deployment and ensures that the stent will expand in the desired position within a body lumen.

The stent delivery system can be used to accurately deliver a stent to a desired location within a patient's vasculature system or other body lumen by preventing unwanted axial motion of the self-expanding stent during the deployment process. The stent delivery system is safe, easy to use and can be quickly and easily removed after the stent has been deployed. The present invention is designed

primarily for use in coronary arteries, however, it may also be used to treat other vessels including the renals, abdominal aorta, femoral, and carotid arteries. Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side elevational view of a preferred embodiment stent delivery system of the present invention;

FIG. 2 is a partial and magnified side elevational view of the distal end of the stent delivery system depicted in FIG. 1;

FIG. 3 is a side elevational view similar to FIG. 1, but showing the sheath in its withdrawn position;

FIG. 4 is a partial and magnified view of the distal end of the stent delivery system depicted in FIG. 3;

FIG. 5 is a cross-sectional view of the distal end of the stent delivery system as shown in FIG. 3 with the sheath withdrawn from the stent;

FIG. 6 is a cross-sectional view taken along line 6-6 of FIG. 5 depicting the catheter and guide wire contained within a lumen of the sheath;

FIG. 7 is a cross-sectional view taken along line 7-7 in FIG. 5 depicting the guide wire slidably disposed within the catheter lumen;

FIG. 8 is a partial perspective view of the manipulator handle included in the preferred embodiment stent delivery system shown in FIG.1;

FIG. 9 is a side elevational view, partially in section, of the manipulator handle shown in FIG. 8;

FIG. 10 is a top plan view of the manipulator handle shown in FIG. 8;

FIG. 11 is a side elevational view of a first embodiment of an attachment device;

FIG. 12 is a side elevational view of a second embodiment of an attachment device;

FIG. 13 is a side elevational view of a third embodiment of an attachment device;

FIG. 14 is an enlarged elevational view of a fourth embodiment of an attachment device;

FIG. 15 is a side elevational view of an alternative embodiment of the present invention stent delivery system;

FIG. 16 is a magnified, side elevational view of a telescopically-adjusting spacing element included in the stent delivery system shown in FIG. 15;

FIG. 17 is a cross-sectional view of the distal end of an alternative embodiment stent delivery system; and

FIG. 18 is a partial, top plan view of the distal end of the stent delivery system depicted in FIG. 17.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the present invention is directed to a stent delivery system having a manipulator handle coupled to a guiding catheter during stent deployment thereby allowing for more accurate stent positioning within a body lumen. Frequently, after balloon angioplasty has been performed to dilate a stenosis in the lumen of a vessel, a self-expanding stent is deployed at the treated site to aid in the healing of dissected arterial lining and to prevent restenosis.

Typically, a self-expanding stent is delivered and deployed by first compressing the stent, mounting the stent at the distal end of a delivery catheter and slidably disposing the catheter and stent within the lumen of a sheath to hold the stent in a contracted condition. Once the catheter and stent are advanced to the desired location within a body lumen, the sheath is retracted to expose the self-expanding stent thereby allowing it to expand against the vessel wall. Examples of stent delivery systems are disclosed in, for example, U.S. Patent Nos. 5,391,172 to Williams et al., and U.S. Patent No. 5,507,768 to Lau et al.

Some conventional stent delivery systems have limitations, because the axial position of the stent might shift within the body lumen while the physician is actuating a switch on the manipulator handle to retract the sheath from the stent. Stent deployment requires precise positioning to be effective. It therefore is an object of the present invention to solve the accuracy problems associated with the prior art method of delivering and deploying self-expanding stents.

FIGS. 1-11 illustrate an exemplary stent delivery system that embodies features of the present invention. In the side elevational views of FIGS. 1-4, the present invention delivery system includes a delivery catheter 10 with a lumen, a

guide wire 12 slidably disposed within a lumen of the delivery catheter 10, and a self-expanding stent 14 mounted on the distal end 11 of the catheter 10. As best can be seen in FIG. 4, the delivery catheter 10 preferably has an elongated catheter body with at least one optional immobile stop 18 that is located on the periphery of the catheter body near the distal end 11 but proximal to the stent 14 in order to prevent the stent 14 from moving proximally relative to the catheter 10. The stop 18 may be an annular protrusion or a simple projection or the like, in order to block the proximal movement of the stent 14.

The catheter 10 and the stent 14 are slidably disposed within an elongated tubular sheath 16, which holds the stent 14 in a contracted condition during advancement through the patient's vasculature. A manipulator handle 20 is provided at a proximal end 13 of the delivery system to effect relative, axial movement between the catheter 10 and the sheath 16. FIGS. 1 and 2 show the delivery system in the state it is in when it is being advanced through the vasculature with the sheath 16 at least partially covering the stent 14. FIGS. 3 and 4 show the delivery system after the sheath 16 has been withdrawn proximally relative to the catheter 10 to expose the self-expanding stent 14.

FIG. 5 is a cross-sectional view of the distal end 11 of the delivery system after the sheath 16 has been withdrawn to expose stent 14. FIGS. 6 and 7 show cross-sections of the delivery system wherein the guide wire 12 is contained within the lumen of the catheter 10 and the catheter 10 is contained within a lumen of the sheath 16.

FIGS. 8-10 depict a preferred embodiment of a manipulator handle 20 located at the proximal end 17 of the sheath of a delivery system according to the present invention. The manipulator handle 20 includes a slidable element 22 on the exterior of a housing 24, which is attached to the stem 30. The stem 30 extends through a slot 26 in the wall of the housing 24 and is secured to the proximal end 17 of the tubular sheath 16. The stem 30 is received in a close-fit relationship through the slot 26. As is best illustrated in the plan view of FIG. 10, the slot 26 in the wall

of the housing 24 has narrowed portions 28 near both ends of the slot which have widths just slightly smaller than the width of the stem 30 such that the slidable element 22 can be locked into position.

The manipulator handle 20 preferably is secured to the proximal end 15 of the delivery catheter 10 using a means such as a Luer lock 32. Within the housing 24 of the manipulator handle 20, and starting at the proximal end 15 of the manipulator handle, the catheter 10 extends distally and enters a lumen at the proximal end 17 of the tubular sheath 16.

To facilitate gripping, the underside of the manipulator handle housing 24 optionally may be provided with an undulating surface 34 which is adapted to receive the fingers of a physician. The sheath 16, with the catheter 10 slidably disposed in its lumen, emerges from a port 36 at the distal end 19 of the manipulator handle housing 24 and enters the lumen at a proximal end 21 of guiding catheter 38. The guiding catheter 38 facilitates the advancement of the stent delivery system through the patient's vasculature and has a diameter that is large enough to allow the stent delivery system to move freely within in it in a longitudinal direction.

In a preferred embodiment of the present invention depicted in FIGS. 8-10, a coupling arm 40 is carried on the housing 24 of the manipulator handle and is releasably attachable to the proximal end 21 of the guiding catheter 38 once the delivery system has been fully advanced and the stent 14 has been located in the desired axial position within a body lumen. The proximal end 21 of the guiding catheter 38 may include an optional valve with an O-ring seal (not shown), to help stabilize that end as the guiding catheter 38 is slidably adjusted over the sheath 16 when the delivery system is introduced into the patient.

Importantly, the coupling arm 40 provides a means to fix the position of the manipulator handle 20 with respect to the guiding catheter 38. Further, the position of the delivery catheter 10 also is fixed relative to the the manipulator handle 20. Thus, the position of the delivery catheter 10 carrying the stent 14 relative to the

position of guiding catheter 38 can be set precisely. This in turn enables precise deployment of the stent 14 at the target site.

In order to precisely set the relative positions of the manipulator handle 20, the guiding catheter 38, and the delivery catheter 10, the coupling arm 40 has an optional notch 42 that is located at the bottom of the distal end of the coupling arm and which is adapted to receive a tab 44, shown in FIGS. 1 and 2, that is disposed on the exterior of the proximal end 21 of the guiding catheter 38. The tab 44 may be a Luer tab design. With the tab 44 inserted into the notch 42, the coupling arm 40 prevents the manipulator handle 20 from moving relative to the guiding catheter 38. Of course, the length of the coupling arm 40 can be varied using an adjustment means, shown in FIGS. 11-14, to precisely and accurately position the stent 14 at the delivery site.

FIG. 11 illustrates a coupling arm 40 with a rigid proximal section 46 and a rigid distal section 48. The proximal section 46 is received telescopically within a lumen of the distal section 48, and a threaded screw 50 is advanced through a port on the top of the distal section 48 and frictionally engages the proximal section 46. The friction prevents relative movement between proximal and distal sections 46, 48, thus temporarily setting the length of the coupling arm.

The dimensions of a delivery catheter in accordance with the present invention generally will be comparable to the dimensions of delivery catheters used to accomplish angioplasty procedures in like locations in the body lumen, such as the coronary arteries. In the preferred embodiment, the length of a catheter for use in the coronary arteries is about 150 cm and the outer diameter of the catheter is about 0.89 mm (0.035 in.). For carotid and other peripheral procedures, the length of the catheters will range preferably from 60 to 125 cm, with an outside diameter of about 1.78 mm to 2.4 mm (0.070 in. to 0.095 in.)

A tubular sheath according to the invention generally is shorter than the delivery catheter by approximately the length of the manipulator handle. The sheath preferably has an inner diameter that is large enough to accommodate the delivery

catheter and to allow the delivery catheter to move freely therein in a longitudinal direction. The distal end of the sheath preferably has an increased diameter that is suitable to accommodate the self-expanding stent in a contracted condition. The delivery catheter and the sheath can be made of conventional polyethylene tubing, or common engineering polymers such as nylon, PEEK (polyethylene ethyl ketone), or PET (polyethylene terephthalate). The manipulator handle and the coupling arm can be made of conventional materials such as polycarbonate, nylon, or polystyrene.

In operation, the guiding catheter 38 is introduced percutaneously into the cardiovascular system of a patient through, for instance, the femoral artery, and is advanced therein until the distal tip of the guiding catheter is just proximal to the vessel site to be treated. Typically, the guiding catheter 38 is advanced until it is disposed in the ostium of a coronary artery. The stent delivery system is introduced through the guiding catheter 38 with the guide wire 12 slidably disposed within the lumen of the catheter 10. When the stent delivery system is advanced to the distal end of the guiding catheter 38, the guide wire 12 is extended out from the catheter 10 and is advanced to, or just past, the site at which it is desired to deploy the stent. Thereafter, the catheter 10 and the stent 14 are advanced over the guide wire 12 by pushing forward on the manipulator handle 20 until the stent 14 is positioned at the desired location.

Once the stent delivery system is in position, the coupling arm 40 which is carried on the manipulator handle 20 is adjusted in length by rotating the screw 50 such that the proximal section 46 and the distal section 48 of the coupling arm 40 are free to move relative to each other. At this point, the notch 42 on the coupling arm is placed onto the tab 44 located on the guiding catheter 38 to anchor the manipulator handle 20 to the guiding catheter 38. The screw 50 on coupling arm 40 then is tightened to engage frictionally the proximal section 46 of the coupling arm 40 and thereby to prevent relative movement of the two sections 46, 48. While the screw 50 is in the tightened state, there can be no relative axial movement between manipulator handle 20 and the guiding catheter 38.

Importantly, as mentioned above, with the position of the manipulator handle 20 being fixed relative to the guiding catheter 38, the position of the stent 14 mounted on the distal end of the delivery catheter 10 also is fixed relative to the guiding catheter 38 and, therefore, the stent and the delivery catheter should remain stationary within the body lumen, even when the stent is being deployed. It should be clear that the coupling arm 40 serves as a stabilizing component in a stent delivery system according to the present invention.

To deploy the self-expanding stent 14, to achieve a secure grip the physician first grasps the manipulator handle 20 by wrapping his or her finger along the undulating surface 36 and placing a thumb on the slidable element 22. The physician then moves the slidable element 22 proximally relative to the manipulator handle 20 while using a fluoroscope to view the site at which the stent is to be deployed. When the slidable element 22 is moved proximally, the sheath 16 is withdrawn proximally relative to both the catheter 10 and the self-expanding stent 14. While the sheath 16 is being withdrawn, the stent 14 is prevented from sliding proximally along the catheter 10 by at least one immobile stop 18 which is disposed on the periphery of the catheter 10.

With the coupling arm 40 attached to the guiding catheter 38, the physician is free to push against the manipulator handle 20 in order to produce enough force to pull back on the slidable element 22 without concern that this action will dislodge the axial position of the catheter 10 or the stent 14. As the slidable element 22 is pulled back, the stem 30 passes through the narrowed portion 28 of the slot 26 in the housing 24 of the manipulator handle 20 and locks the sliding element 22 into the position corresponding to a fully withdrawn sheath.

With the sheath 16 withdrawn, the self-expanding stent 14 no longer is restrained in a contracted state and therefore expands against the vessel walls. After the stent 14 has deployed fully, the coupling arm 40 is disconnected from the guiding catheter 38 and the delivery system is withdrawn from the patient's body

with the stent 14 remaining in the vessel lumen to maintain the patency of the treated vessel.

FIGS. 12-15 show various alternative embodiments of the coupling arm which is used to attach the manipulator handle 20 to the guiding catheter 38. FIG. 12 is an embodiment that is similar to the preferred embodiment, but is one in which teeth 56 are provided both on the lower portion of the proximal section 52 of the coupling arm and in the lumen provided in the distal section 54 of the coupling arm. The teeth 56 further help to prevent relative motion between the proximal and distal sections 52, 54. A threaded screw 50 is used to secure the sections frictionally.

FIG. 13 illustrates a third embodiment of a coupling arm in which a proximal section 58 and a distal section 60 of the coupling arm are connected with a rotatable member 62. Either or both of the proximal section 58 and the distal section 60 can be threaded so that when the rotatable member 62 is turned, the proximal section 58 and the distal section 60 are either drawn together or pushed apart (depending on the direction in which the rotatable member 62 is turned).

FIG. 14 illustrates a fourth embodiment of a coupling arm in which a threaded screw 68 extends through a lumen in the proximal section 64, then out of the distal end of the proximal section 64 and into the proximal end of the distal section 66. The screw 68 cannot be moved axially within the proximal portion 64 but can be rotated freely therein so as to engage the complementary threads that are provided in the distal portion 66. Rotating the screw 68 either pulls the distal section 66 closer or pushes the distal section away, depending on the direction of rotation, and thus changes the length of the coupling arm.

In still another embodiment of the present invention, as is illustrated in FIG. 15, a coupling spacer 70 is provided which extends between the manipulator handle 20 and the guiding catheter 38. The coupling spacer 70 engages a distal end 19 of the manipulator handle 20 and the proximal end 21 of the guiding catheter 38 in order to prevent the manipulator handle 20 from moving distally relative to the guiding catheter 38. Therefore, with the coupling spacer 70 in place, a distal force

can be applied to the manipulator handle 20 without inadvertently moving the manipulator handle 20 in the distal direction.

The coupling spacer 70 preferably is composed of an outer tube 72 and an inner tube 74, the outer tube 72 adapted to receive telescopically the inner tube 74. The outer portion of the inner tube 74 and the inner portion of the outer tube 72 are threaded such that the outer and inner portions may be rotated relative to one another in order to adjust the width of the coupling spacer as needed. This feature can be appreciated with reference to FIG. 16.

FIGS. 17-18 illustrate a stent delivery system according to the present invention which is configured for rapid exchange as opposed to over-the-wire advancement and withdrawal. As is shown in FIG. 17, a plug 76 is located in the lumen of the catheter 10 which prevents the guide wire 12 from extending proximally through the catheter lumen. An optional ramp 78 is located on the distal side of the plug 76 in order to force the guide wire 12 out of the lumen of the catheter 10 and through the port 86 in the wall of the catheter 10. The guide wire 12 then extends out of the slot 80 that is formed in the wall of the sheath 84. Similar to the other embodiments, an immobile stop 18 is located proximal to the stent 14 in order to prevent the stent 14 from shifting out of position as the sheath 84 is withdrawn. As illustrated in FIG. 18, a slit 82 extends from a port 86 in the wall of the sheath 84 through to the distal end of the sheath 84.

From the foregoing, it will be appreciated that a stent delivery system according to the present invention allows self-expanding stents to be deployed while preventing any unwanted axial movement of the stent during deployment. The invention is made of materials that are commonly found in the industry today and is simple to use and easy to manufacture. While particular embodiments of the present invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the scope of the invention.

Claims

WHAT IS CLAIMED IS:

1. A delivery system for implantation of a self-expanding stent within a body lumen, comprising:

a delivery assembly including

an elongated catheter having proximal and distal ends, the distal end configured to receive on an exterior thereof the self-expanding stent;

an elongated sheath having proximal and distal ends and formed with a lumen to slidably receive the catheter, and having an open-ended receptacle at the distal end for receiving the self-expanding stent;

a manipulator having a stem axially movable relative to the manipulator, the stem connected to the proximal end of the sheath to adjust an axial position of the sheath relative to the catheter, and wherein the proximal end of the catheter is selectively positioned to engage the manipulator; and

a stop disposed on an exterior of the catheter proximal to the self-expanding stent to prevent the stent from moving proximally during relative movement between the sheath and the catheter; and

a guiding catheter having a proximal end, and formed with a lumen for receiving the delivery assembly therein, and wherein the proximal end is connected to the manipulator.

2. A delivery system as set forth in claim 1, wherein the sheath is formed with a cylindrical body of a first diameter and the receptacle has a second diameter larger than the first diameter.

3. A delivery system as set forth in claim 1, wherein the sheath includes a material selected from the group consisting of polyethylene, nylon, PEEK, or PET.

4. A delivery system as set forth in claim 1, wherein the catheter further comprises an inner lumen within the catheter adapted to receive a guide wire therethrough.

5. A delivery system as set forth in claim 1, wherein the stop includes an annular shape.

6. A delivery system as set forth in claim 1, wherein the catheter includes a sideport for receipt of a guide wire.

7. A delivery system as set forth in claim 1, wherein the manipulator further comprises a handle having a hollow tube receiving the proximal end of the sheath, the handle including an elongated slot through which the stem extends, and the handle having a distal end adjustably connected to the proximal end of the sheath.

8. A delivery system as set forth in claim 7, wherein the elongated slot is formed at the proximal and distal ends with a neck down portion for frictionally engaging the stem.

9. A delivery system as set forth in claim 1, wherein the proximal end of the catheter is connected to the proximal end of the guiding catheter, and the connection includes proximal and distal sections wherein the distal section includes an open ended bore that receives the distal end of the proximal section and further

includes a rotatable screw that enters the distal section through a port and frictionally engages the proximal section to the distal section.

10. A delivery system as set forth in claim 9, wherein the proximal and distal sections include teeth for resisting lateral movement.

11. A delivery system as set forth in claim 1, wherein the system further comprises connecting the proximal end of the catheter to the proximal end of the guiding catheter and the connection includes proximal and distal sections configured with axially disposed, aligned threaded studs, further including a rotatable member with bores for receipt of the studs.

12. A delivery system as set forth in claim 1, wherein the proximal end of the catheter is connected to the proximal end of guiding catheter and the connection includes proximal and distal sections wherein an axial bore is formed in the proximal and distal sections and further includes a rotatable screw for engaging threads in the distal section.

13. A delivery system for implanting a self-expanding stent within a body lumen, comprising:

an elongated catheter having a proximal end and a distal end, wherein the stent is disposed on the catheter at the distal end;

a sheath having a proximal end and an open distal end, coaxially and slidably disposed over the elongated catheter, wherein the open distal end overlies the stent;

a manipulator selectively positioning the proximal end of the catheter, the manipulator further including a radial stem connected to the proximal end of the sheath, wherein movement of the radial stem translates the sheath relative to the catheter; and

a guiding catheter having a proximal end and a lumen adapted to receive the sheath, catheter, and stent therein, wherein the proximal end is connected to the manipulator.

14. The delivery system of claim 13, wherein the catheter includes an immobile stop disposed proximal to the stent.

15. The delivery system of claim 13, wherein the manipulator further comprises a distal section connected to the guiding catheter and a proximal section connected to the catheter, and wherein the distal section and proximal section are coaxially aligned to telescope.

16. The delivery system of claim 13, wherein the proximal end of the guiding catheter is spaced apart from the manipulator, and the system includes a telescoping spacer bar connecting the manipulator to the proximal end of the guiding catheter.

17. The delivery system of claim 13, wherein the proximal end of the guiding catheter is spaced apart from the manipulator, and the system includes telescoping spacers disposed coaxially over the proximal end of the catheter between the manipulator and the proximal end of the guiding catheter.

18. The delivery system of claim 16, wherein the guiding catheter includes tabs at the proximal end thereof that engage the spacer bar.

19. The delivery system of claim 15, wherein the telescoping distal section and proximal section include a radially extending threaded screw.

20. A method for delivering for implantation a self-expanding stent within a body lumen, comprising:

providing an elongated catheter having a proximal end and a distal end;

disposing the stent on the catheter at the distal end;

slidably disposing a sheath having a proximal end and an open distal end coaxially over the elongated catheter so that the open distal end at least partially overlies the stent;

providing a manipulator having a stem connected to the proximal end of the sheath;

connecting the proximal end of the catheter to the manipulator;

providing a guiding catheter having a lumen adapted to receive the sheath, catheter, and stent therein;

providing telescoping spacers connected to the manipulator and to the guiding catheter at opposite ends; and

displacing the stem to slidably translate the sheath relative to the catheter to expose the stent.

21. The method of claim 20, wherein the step of providing a manipulator further comprises:

providing a manipulator housing receiving the proximal end of the catheter and sheath therethrough;

forming am opening in the manipulator housing; and

passing the stem through the opening wherein movement of the stem within the opening translates the sheath relative to the catheter.

22. The method of claim 20, wherein the step of providing telescoping spacers further comprises providing a threaded screw passing radially into the telescoping spacers.

23. The method of claim 20, wherein the step of providing telescoping spacers further comprises providing a threaded screw passing axially through one spacer into the other.

24. The method of claim 20, wherein the step of providing telescoping spacers further comprises providing a spacer having external threads engaging an internally-threaded rotatable connecting member at one end, and the rotatable connecting member is rotatably connected to the other spacer at another end.

25. The method of claim 20, wherein the method further comprises providing a stop on the catheter immediately proximal to the stent.

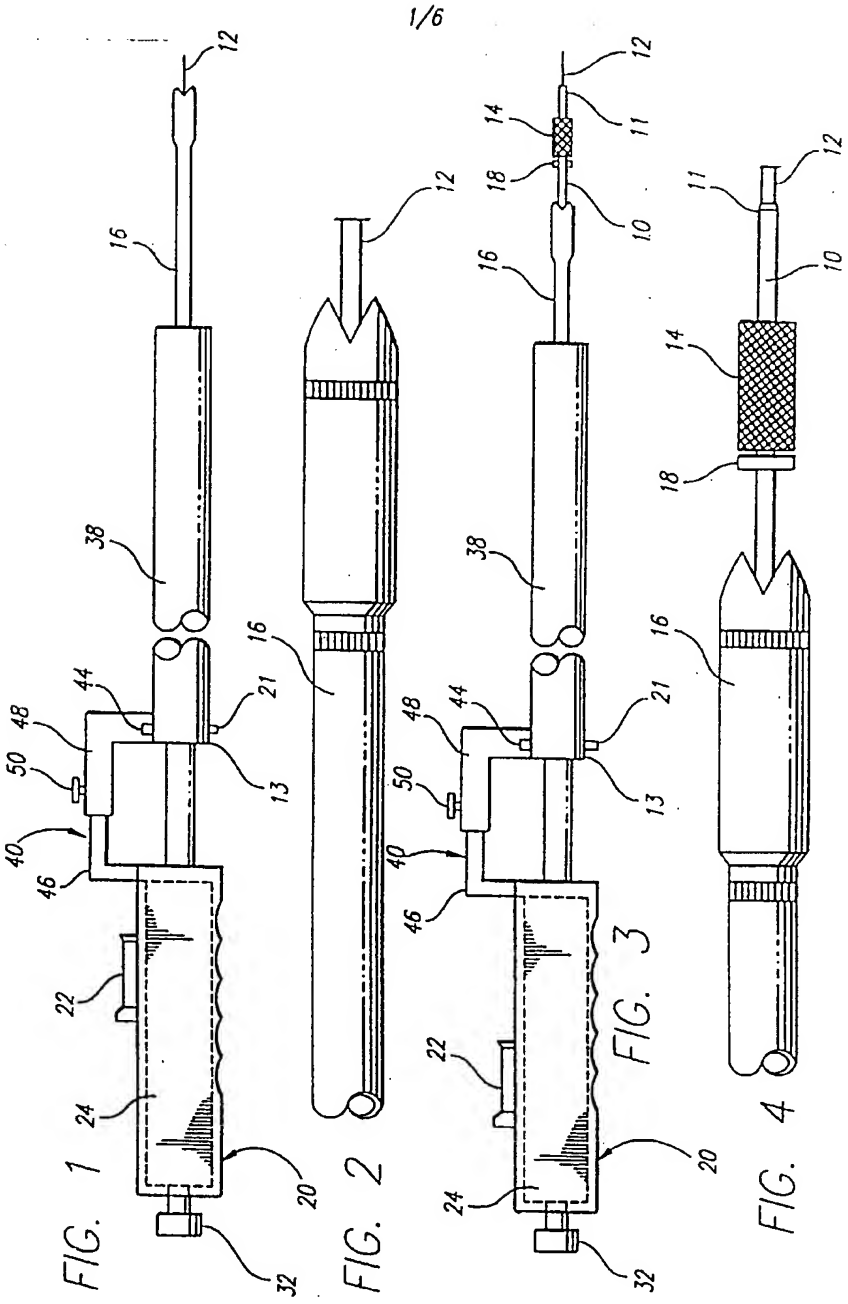


FIG. 1

FIG. 2

FIG. 3

FIG. 4

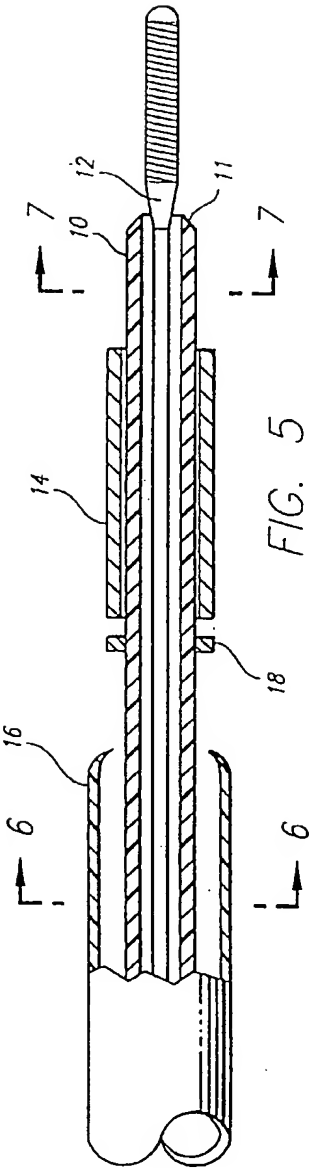


FIG. 5

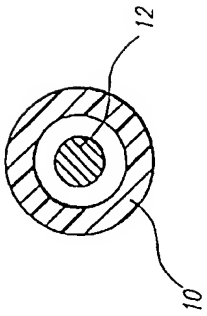


FIG. 7

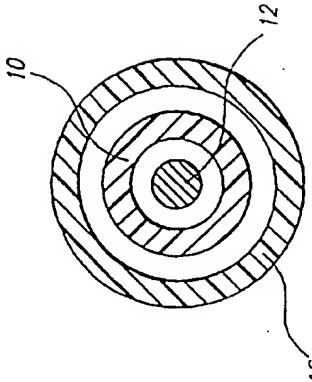


FIG. 6

FIG. 8

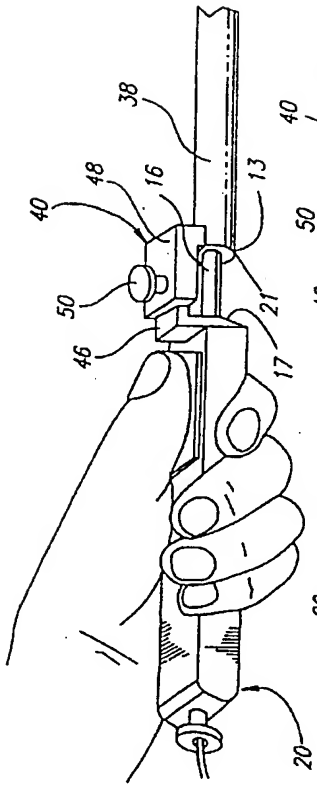


FIG. 9

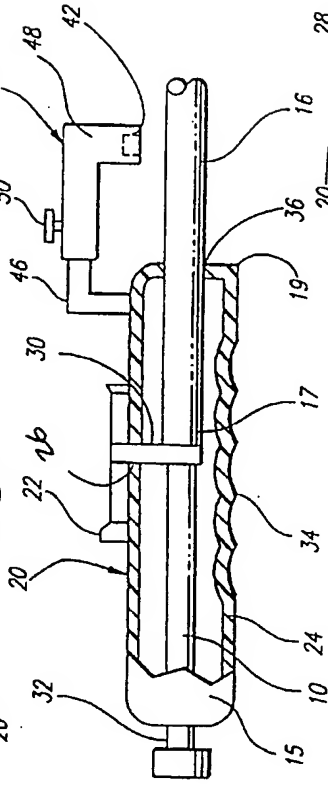
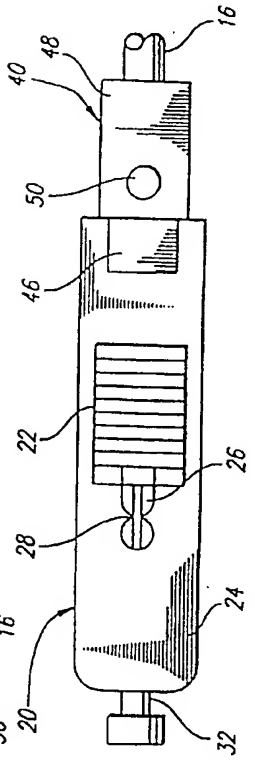


FIG. 10



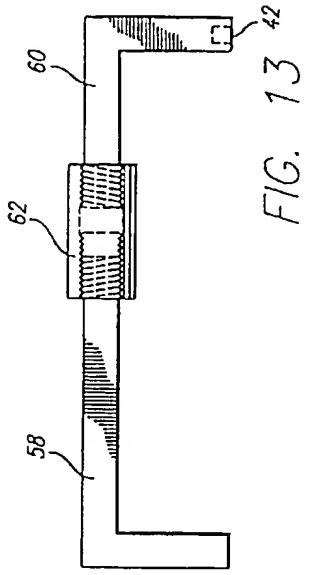


FIG. 13

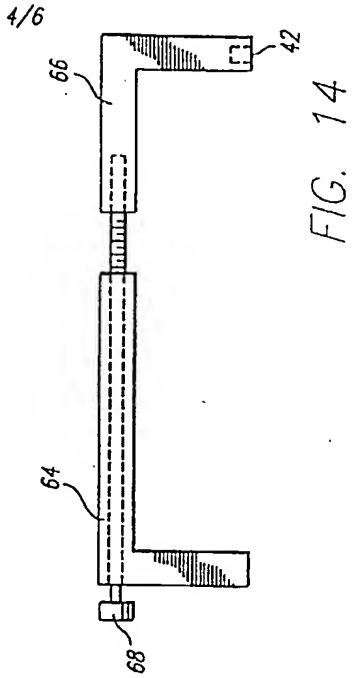


FIG. 14

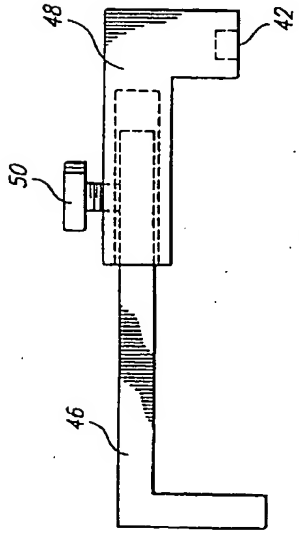


FIG. 11

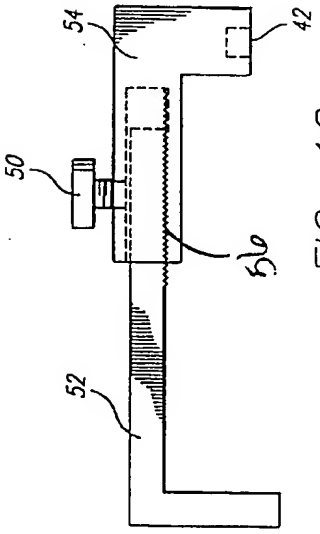


FIG. 12

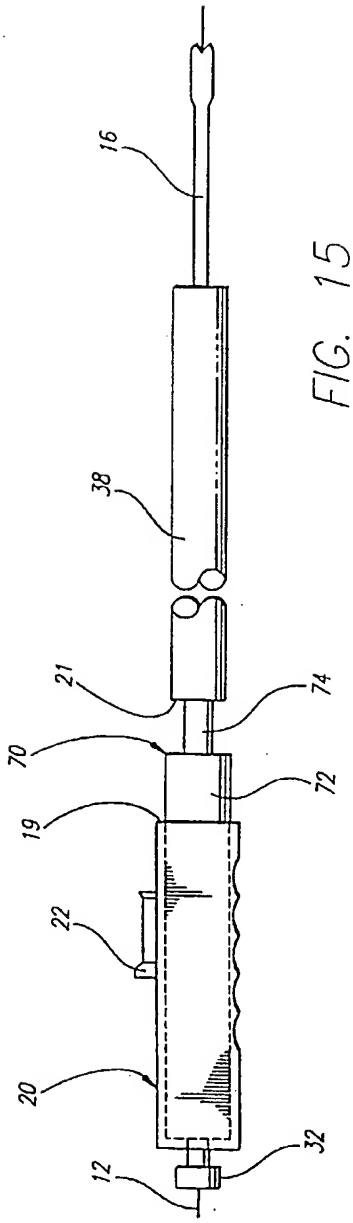


FIG. 15

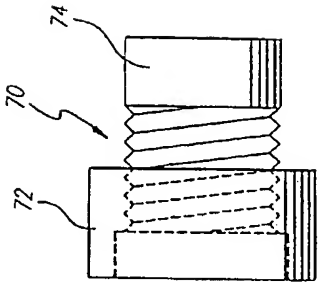


FIG. 16

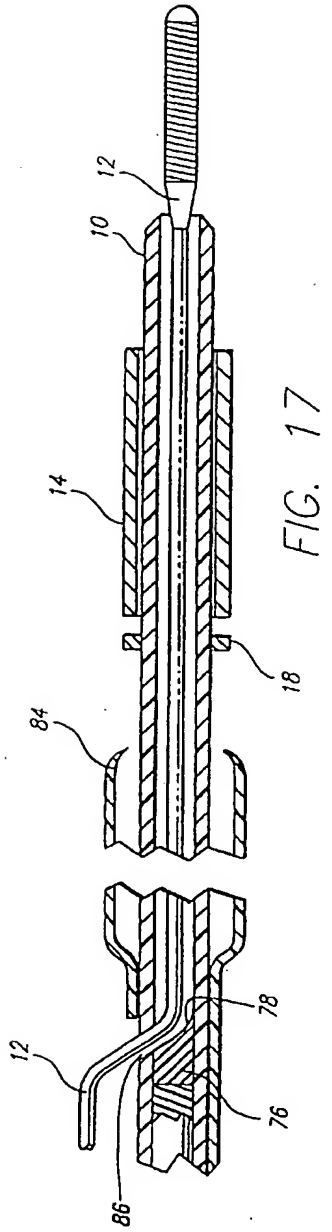


FIG. 17

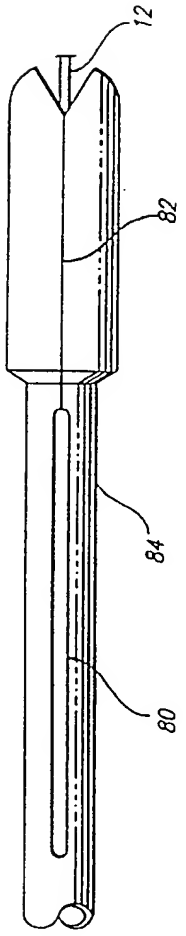


FIG. 18

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/11974

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 627 201 A (SCHNEIDER EUROP AG) 7 December 1994 (1994-12-07) figures 1-4 column 3, line 27 -column 4, line 29 ---	1,4,5, 13,14
A	US 5 776 142 A (GUNDERSON RICHARD C) 7 July 1998 (1998-07-07) claims 1-3; figures 1,7-9 ---	1,2,4-7, 9,11,13, 15-17,19
A	US 5 507 768 A (SIGWART ULRICH ET AL) 16 April 1996 (1996-04-16) cited in the application claims 1-5; figures 6,11,12 ---	1,3,4, 6-8,13
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 August 2000	05. 10. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Stach, R

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/11974

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 391 172 A (YAMBAO AUGUST ET AL) 21 February 1995 (1995-02-21) cited in the application figures 1,3,4 column 2, line 49 -column 3, line 24 -----	1,4,6-8, 13

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Ir ·ational application No.
PCT/US 00/11974

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20-25
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/11974

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